

K123289



Cardinal Health

1430 Waukegan Road
McGraw Park, IL 60085

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FEB 28 2013

510(k) SUMMARY
DuraBlue™ Sterilization Wrap

Manufacturer: Cardinal Health 200, LLC
1430 Waukegan Road
McGraw Park, IL 60085

Regulatory Affairs Contact: Lavenia Ford
1430 Waukegan Road
McGraw Park, IL 60085

Telephone Number: (847) 887-3323

Date summary Prepared: February 12, 2013

Trade Name: DuraBlue™ Sterilization Wrap

Classification: Class II per 21 CFR § 880.6850

Classification Name: Sterilization Wrap

Common Name: Sterilization Wrap

Product Code: FRG

Predicate Device: K112211 - DuraBlue™ Sterilization Wrap – Pre-vacuum Steam (4 min/270°C)
K120542 - DuraBlue™ Sterilization Wrap – Ethylene Oxide(EO) (725-735 mg/L at 55°C/40%-80%RH/60 min)

Description:

Cardinal Health DuraBlue™ Sterilization Wraps are double layer sterilization wraps made from 100% polypropylene spunbond-meltblown-spunbond (SMS) fabric. They are intended to be used to enclose another medical device that is to be sterilized by a health care provider pre-vacuum steam at 270°F/132°C for 4 minutes, or 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes. This wrap design allows for use of the simultaneous double-wrapping technique and also allows for a sterilized pack to be opened aseptically.

The only modification to the predicate devices involving the clarification of the sterility maintenance information provided in the Indication for Use portion of the Instructions for Use Labeling.

- Predicate Statement:
 - "The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) for 30 days."
- Proposed Statement:
 - "The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s). Maintenance of package sterility was validated with real-time aging testing for a duration of 180 days for each indicated modality."

This modification is based on Event-Related Shelf Life testing that demonstrates that the DuraBlue™ Sterilization Wrap maintains sterility of the enclosed contents for 180 days following sterilization by pre-vacuum steam or EO.

This submission covers six different models of Cardinal Health DuraBlue™ Sterilization Wrap. Each model is made from material of a different basis weight, though all models utilize the same material technology.

Table 1: Overall Comparison to Predicate Devices

Element of Comparison	PROPOSED Cardinal Health DuraBlue™ Sterilization Wrap – Pre-vacuum Steam or EO	PREDICATE Cardinal Health DuraBlue™ Sterilization Wrap – Pre-vacuum Steam (K112211)	PREDICATE Cardinal Health DuraBlue™ Sterilization Wrap – Ethylene Oxide (EO) (K120542)
Key Claims	<ul style="list-style-type: none"> 180 day Maintenance of Sterility Testing for all modalities 	<ul style="list-style-type: none"> Indications for use with pre-vacuum sterilization 	<ul style="list-style-type: none"> Indications for use with Ethylene Oxide sterilization
Product Properties	100% polypropylene spunbond-meltblown-spunbond (SMS) fabric	Same	Same
Intended Use	<p>Cardinal Health DuraBlue™ Sterilization Wrap is intended to enclose another medical device that is to be sterilized by a health care provider using the following modalities:</p> <ul style="list-style-type: none"> pre-vacuum steam at 270°F/132°C for 4 minutes 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes <p>The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s). Maintenance of package sterility was validated with real-time aging testing for a duration of 180 days following each indicated modality.</p> <p>For pre-vacuum steam sterilization, the wrap has been validated for dry times of 20 minutes for Models CH100 and CH200 and 30 minutes for Models CH300, CH400, CH500, and CH600.</p> <p>For EO sterilization, the wrap has been validated for an aeration time of 8 hours at 55°C.</p>	<p>Cardinal Health DuraBlue™ Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider by pre-vacuum steam at 270°F/132°C for 4 minutes. The wrap is not indicated for use with gravity steam sterilization.</p> <p>The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed devices for 30 days.</p> <p>The wrap has been validated for dry times for pre-vacuum steam sterilization of 20 minutes for Models CH100 and CH200, and for 30 minutes for Models CH300, CH400, CH500 and CH600.</p>	<p>Cardinal Health DuraBlue™ Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider by 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes.</p> <p>The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed devices for 30 days. The wrap has been validated for an aeration time of 8 hours at 55°C.</p> <p>Models CH400, CH500, and CH600 have been validated for sterilization of two lumens of 3 mm diameter or larger and 400 mm in length or less for EO sterilization.</p>
Length of Maintenance of Sterility Testing	<p><u>Pre-vacuum steam:</u> 180 days</p> <p><u>Ethylene oxide:</u> 180 days</p>	<u>Pre-vacuum steam:</u> 30 days	<u>Ethylene oxide:</u> 30 days
Lumen Claims	<p><u>Pre-vacuum steam:</u> Models CH400, CH500 and CH600 have been validated for sterilization of two lumens of 3mm diameter or larger and 400mm in length or less.</p> <p><u>Ethylene Oxide (EO):</u> Same as K120542</p>	<u>Pre-vacuum Steam:</u> Models CH400, CH500 and CH600 have been validated for sterilization of lumens of 3mm diameter or larger and 400mm in length or less.	<u>Ethylene Oxide (EO):</u> Models CH400, CH500, and CH600 have been validated for sterilization of two lumens of 3mm diameter or larger and 400mm in length or less.

Indications for Use:

Cardinal Health DuraBlue™ Sterilization Wrap is intended to enclose another medical device that is to be sterilized by a health care provider using the following modalities:

- Pre-vacuum steam at 270°F/132°C for 4 minutes
- 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes

The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s). Maintenance of package sterility was validated with real-time aging testing for a duration of 180 days for each indicated modality.

For pre-vacuum steam sterilization, the wrap has been validated for dry times of 20 minutes for Models CH100 and CH200 and 30 minutes for Models CH300, CH400, CH500, and CH600. Models CH400, CH500, and CH600 have been validated for pre-vacuum steam sterilization of two lumens 3 mm in diameter or larger and 400 mm in length or less.

For EO sterilization, the wrap has been validated for an aeration time of 8 hours at 55°C. Models CH400, CH500, and CH600 have been validated for sterilization of two lumens of 3 mm diameter or larger and 400 mm in length or less for EO sterilization.

Table 2 - Wrap Model Recommendations

Sterilization Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content Weight
		Pre-Vacuum Steam and EO
CH100	Very light weight package (for example: batteries)	3 lbs
CH200	Light weight package (for example: telescope with light cord)	6 lbs
CH300	Light to moderate weight package (for example: general use medical instruments)	9 lbs
CH400	Moderate to heavy weight package (for example: general use medical instruments)	13 lbs
CH500	Heavy weight package (for example: general use medical instruments)	17 lbs
CH600	Very heavy weight package (for example: general use medical instruments)	25 lbs

The following loads were used in the pre-vacuum steam Sterility Validation Studies:

- CH100: 16 huck towels (17 in. x 29 in.).
- CH200: 2 huck towels (17 in. x 29 in.), 3 fluid-resistant drapes (108 in. x 72 in.).
- CH300: 16 huck towels (17 in. x 29 in.), 1 fluid-resistant table cover (90 in. x 60 in.), 5 lbs of metal mass.
- CH400: 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 8 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- CH500: 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 12 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- CH600: 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 20 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.

The following loads were used in the EO Sterility Validation Studies:

- CH100: 16 huck towels (17 in. x 29 in.).
- CH200: 2 huck towels (17 in. x 29 in.), 2 fluid-resistant drapes (108 in. x 88 in.), 2.5 lbs of metal mass.
- CH300: 16 huck towels (17 in. x 29 in.), 1 fluid-resistant table cover (90 in. x 60 in.), 5 lbs of metal mass.
- CH400: 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 7.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- CH500: 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 11.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- CH600: 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 19.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.

Note: The loads used in the Sterility Validation Study corresponded to the maximum wrapped package content weights in Table 2.

Substantial Equivalence

The proposed DuraBlue™ Sterilization Wrap is substantially equivalent to the predicate devices. Both devices:

- Have the same intended use
- Have the same material composition
- Have the same physical and chemical properties
- Have the same configurations/dimensions
- Are indicated for the same sterilization parameters
- Are indicated for the same Maximum Wrapped Package Content Weights

Summary of Testing

DuraBlue™ Sterilization Wrap performance has been tested in accordance with the applicable requirements recommended in the FDA's Guidance Document *Premarket Notification 510(k) Submissions for Medical Sterilization Packaging System in Health Care Facilities; Draft Guidance for Industry and FDA* (March 7, 2002) in the predicate Premarket Notifications. Testing included sterilization efficacy, physical properties, event related maintenance of package sterility, and biocompatibility in compliance with the methods of ISO 10993 for pre-vacuum steam and EO. Data from testing demonstrates that the DuraBlue™ Sterilization Wrap maintains sterility of the enclosed contents for 180 days following sterilization by pre-vacuum steam and EO.

Table 3: Performance Testing of Proposed DuraBlue Sterilization Wrap sterilized by Pre-vacuum steam or EO

Performance Properties		Results
Sterilization Efficacy		PASS
Microbial Barrier Properties	Aerosol Challenge	PASS
	Event Related Shelf Life	PASS- 180 days
Material Compatibility with Indicated Sterilization Method		Compatible
Biocompatibility		PASS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2013

Cardinal Health-Medical Products and Services
C/O Mr. Ned Devine
Underwriters Laboratories, Incorporated
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K123289

Trade/Device Name: Cardinal Health DuraBlue™ Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: February 15, 2013
Received: February 19, 2013

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 **Kwame O. Ulmer** for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



CardinalHealth

Indications for Use

510(k) Number (if known): K123289

Device Name: Cardinal Health DuraBlue™ Sterilization Wrap

Indications for Use:

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- Pre-vacuum steam at 270°F/132°C for 4 minutes
- 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes

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For EO sterilization, the wrap has been validated for an aeration time of 8 hours at 55°C. Models CH400, CH500, and CH600 have been validated for sterilization of two lumens of 3 mm diameter or larger and 400 mm in length or less for EO sterilization.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Shani J. Smith, _____ Concurrency of CDRH, Office of Devices Evaluation (ODE)

2013.02.28 15:52:20-05'00'

Division Sign-Off

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) _____

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- **CH500:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 12 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.
- **CH600:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 20 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.

The following loads were used in the EO Sterility Validation Studies:

- **CH100:** 16 huck towels (17 in. x 29 in.).
- **CH200:** 2 huck towels (17 in. x 29 in.), 2 fluid-resistant drapes (108 in. x 88 in.), 2.5 lbs of metal mass.
- **CH300:** 16 huck towels (17 in. x 29 in.), 1 fluid-resistant table cover (90 in. x 60 in.), 5 lbs of metal mass.
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- **CH600:** 4 stacked tray liners (20 in. x 25 in.), 2 lumens (3 mm I. D x 400 mm), and 19.5 lbs of metal mass in a 23 in. x 11 in. x 3.5 in. tray.

Note: The loads used in the Sterility Validation Study corresponded to the maximum wrapped package content weights in Table 1.